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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/759,902	01/16/2004	John R. Helland	A04P1003	8467
36802	7590	07/20/2006	EXAMINER	
PACESETTER, INC. 15900 VALLEY VIEW COURT SYLMAR, CA 91392-9221			HOLMES, REX R	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 07/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/759,902

Applicant(s)

HELLAND ET AL.

Examiner

Rex Holmes

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 January 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) 9-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01/16/04 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>01/16/04</u> . | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-8, drawn to an apparatus, classified in class 607, subclass 116.
  - II. Claims 9-11, drawn to a method, classified in class 607, subclass 117.
2. The inventions are distinct, each from the other because of the following reasons:  
Inventions Group 2 and Group 1 are related as process and apparatus for its practice.  
The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus as claimed can be used to practice another and materially different process such as delivering a dye, drug, or saline solution through the one or more channels. The method does not require the delivery of an adhesive.
3. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.
4. During a telephone conversation with Derrick Reed on 7/10/06 a provisional election was made without traverse to prosecute the invention of Group 1, claims 1-8. Affirmation of this election must be made by applicant in replying to this Office action. Claims 9-11 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Information Disclosure Statement***

6. The information disclosure statement filed 01/16/2004 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein that has been struck-through has not been considered.

### ***Drawings***

7. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "570" has been used to designate both the "Mechanics Module" and the "Connector Module" in Figure 5. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of

an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

8. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: "716" in Figure 7, "816" in Figure 8, and "916" in Figure 9. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

9. In addition to Replacement Sheets containing the corrected drawing figure(s), applicant is required to submit a marked-up copy of each Replacement Sheet including annotations indicating the changes made to the previous version. The marked-up copy must be clearly labeled as "Annotated Sheets" and must be presented in the amendment or remarks section that explains the change(s) to the drawings. See 37

CFR 1.121(d)(1). Failure to timely submit the proposed drawing and marked-up copy will result in the abandonment of the application.

### ***Specification***

10. The use of the trademarks AVITENE, SURGICEL, GELFOAM, FIBRX, and FOCALSEAL have been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

### ***Claim Rejections - 35 USC § 102***

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated by CROWLEY (U.S. Pat. 6,004,269).

13. Regarding Claim 1, CROWLEY teaches a lead (Fig. 1) with a conductor (Fig. 51, 634), an electrode (Fig. 50, 621) and a channel (Fig. 51, 620).

14. Examiner notes the limitation "that allows for the flow of adhesive or an adhesive component to the nerve to establish electrical contact between the nerve and the at

least one electrode", is only functional language and only requires the capability to so perform. Here the channel (Fig. 51, 620, 632) is capable of being used to allow adhesive to flow to the nerve and electrodes, because CROWLEY discloses that the channels allow for other liquids such as saline to be passed through the channel.

15. Regarding Claim 2, CROWLEY teaches the use of multiple electrodes (Fig. 50, 621, 635, 636).

16. Regarding Claim 3, CROWLEY teaches the use of radiation and the delivery of its use to the site of the lead (Fig. 69, 790, 792 and as discussed in the specification Column 4, Lines 38-42, and Column 29, Lines 16-18).

17. Regarding Claim 4, CROWLEY teaches the use of electrical/magnetic radiation (Column 4, Lines 38-42).

18. Regarding Claim 5, CROWLEY teaches the use of more than one channel in the lead body (Fig. 51, 620, 632).

19. Regarding Claim 6, CROWLEY teaches that the radiation conduit is housed within the lead body (Fig. 69).

20. Regarding Claim 7, CROWLEY teaches that there is a shaft/sheath surround the lead body (Fig. 36, 510).

### ***Claim Rejections - 35 USC § 103***

21. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

22. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

23. Claim 8 is rejected under 35 U.S.C. 102(b) as anticipated by CROWLEY or, in the alternative, under 35 U.S.C. 103(a) as obvious over CROWLEY in view of GIELE (U.S. Pat. 6,004,269).

24. Regarding Claim 8, CROWLEY teaches that the shaft/sheath is constructed to have torqueability (Column 34, Lines 38-39), in other words be able to be handle a turning or twisting force. Therefore, providing a sheath rotatable with respect to the lead.

25. In the alternative, CROWLEY teaches an outer shaft that has torqueability. However, CROWLEY does not explicitly state that the shaft is rotatable with respect to the lead body.

26. GIELE teaches an electrical lead surrounded by an outer sheath. It also teaches that the lead body is rotatable within the outer sheath. (Column 8, Lines 57-60).



27. CROWLEY discloses the claimed invention except for the lead body explicitly being rotatable within the outer sheath. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the lead as taught by CROWLEY, with rotatable outer sheath of GIELE since it was known in the art that rotatable outer sheaths are used to provide placement of medical leads and electrodes in a proper position in the heart.

***Conclusion***

28. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure as listed on the PTO-892. WHITE (U.S. Pat. 4,360,031) is one of the many patents showing the use of open channels in leads to deliver fluid to site of the electrode(s). Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rex Holmes whose telephone number is 571-272-8827. The examiner can normally be reached on M-F 8:00 - 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

~ ~  
GEORGE R. EVANISKO  
PRIMARY EXAMINER

2/12/6

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in black ink, appearing to read 'Rex Holmes', with a stylized flourish at the end.

Rex Holmes

George Evanisko

Primary Examiner